

CONSENT FORM

HIPAA Compliant

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

H-40275- POSTERIOR ANKLE ARTHROSCOPY IN PEDIATRIC POPULATION- INDICATIONS, MANAGEMENT AND OUTCOMES

H-40275- POSTERIOR ANKLE ARTHROSCOPY IN PEDIATRIC POPULATION- INDICATIONS,
MANAGEMENT AND OUTCOMES

Background

You are invited to take part in a research study. Please read this information and feel free to ask any questions before you agree to take part in the study. A research study is a way that doctors look at the outcome of a specific treatment, such as patients undergoing posterior ankle arthroscopy. Research studies include only people who choose to take part.

You are being asked to let your child take part in this study because he/she is undergoing posterior ankle arthroscopy. This study will evaluate the long-term clinical and radiographic outcomes of patients undergoing posterior ankle arthroscopy. The study build a registry of patients that undergo posterior ankle arthroscopy at Texas Children's Hospital.

Participation is voluntary and your participation will have no effect on your clinical care. Please take your time to make your decision. Please be sure to ask any questions that you may have.

Purpose

The purpose of this study is to compare the results of different treatments for patients that undergoes posterior ankle arthroscopy. This study will help us understand which treatment works the best.

You are being asked to take part in this study because you are between the ages of 2 and 18 years old and are undergoing posterior ankle arthroscopy.

Procedures

The research will be conducted at the following location(s):
Baylor College of Medicine and TCH: Texas Children's Hospital.

All of this important information will be entered into a secured electronic medical records database, EPIC (Electronic Privacy Information Center) and on Texas Children's Hospital (TCH) encrypt password protected databases were your identity will be hidden. The database server will be maintained behind a firewall at Texas Children's Hospital.

You will not have any additional procedures due to the study. You will still have regular visits with your doctor that will include routine (standard medical care) x-rays or MRIs to follow your treatment. You will have to spend some time (less than 5 minutes per visit) answering questions about your progress after undergoing posterior ankle arthroscopy. You will have standard of care follow up visits (1-2 weeks, 1 month, 3 months, 6 months, and 12 months), until you reach your one year mark.

Patient data will be collected up to 1 year or more after the intervention and will be used for research study purposes.

Again, all information that is collected at these visits will be entered into the EPIC database and TCH encrypt spreadsheet servers.

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Research related health information

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to people who give medical care and ensure quality from Baylor College of Medicine and TCH: Texas Children's Hospital to use or disclose (release) your health information that identifies you for the research study described in this document.

The health information that we may use or disclose (release) for this research includes:

- Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
- Demographic information (name, D.O.B., age, gender, race, etc.)

The health information listed above may be used by and or disclosed (released) to researchers, their staff and their collaborators on this research project, the Institutional Review Board, Baylor College of Medicine, and TCH: Texas Children's Hospital.

Use or Disclosure Required by Law

Your health information will be used or disclosed when required by law.

Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability and conducting public health surveillance, investigations or interventions.

Baylor College of Medicine and TCH: Texas Children's Hospital are required by law to protect your health information. By signing this document, you authorize Baylor College of Medicine and TCH: Texas Children's Hospital to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

Please note that the research does not involve treatment. Baylor College of Medicine and TCH: Texas Children's Hospital may not condition (withhold or refuse) treating you on whether you sign this Authorization.

Please note that you may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers, their staff and their collaborators on this research project, the Institutional Review Board, regulatory agencies such as the U.S. Department of Health and Human Services, Baylor College of Medicine, and TCH: Texas Children's Hospital may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. If you revoke this Authorization, you may no longer be allowed to

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participate in the research described in this Authorization.

To revoke this Authorization, you must write to: Dr. Indranil Kushare, 17580 I-45 South, 4th Floor The Woodlands, TX 77384.

This authorization does not have an expiration date. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

Potential Risks and Discomforts

You should not experience any direct health risk due to participation in this study. You will receive routine care that includes x-rays and MRI. Additionally, your doctor will continue to treat your condition with standard medical treatment. These treatments or procedures may have risks that your doctor will explain to you, but participating in the study does not change the risks.

Any time that information is collected, there is a potential risk of loss of your personal information. Because the study uses EPIC and encrypt databases to store your data every effort will be made to keep your information hidden. To protect your privacy, all data used for research are kept in a secure database. Only the surgeons and research staff will have access to this database. Every effort will be made to prevent the accidental release of information.

Study staff will update you in a timely way on any new information that may affect your decision to stay in the study. There is a small risk for the loss of confidentiality. However, the study personnel will make every effort to minimize these risks.

Potential Benefits

You will receive no direct benefit from your participation in this study. However, your participation may help the investigators better understand pediatric patients undergoing posterior ankle arthroscopy and lead to better ways to treatment these patients.

Alternatives

You may choose to not participate in this study.

Subject Costs and Payments

Neither you nor your insurance provider will be charged for any part of the research study. However, the standard medical care for your condition (care you would receive whether or not you were in the study) is your responsibility or the responsibility of your insurance provider or government program. You will be charged in the standard manner, for any procedures performed for your standard medical care.

You will not be paid for taking part in this study.

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Subject's Rights

Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

The investigator, INDRANIL KUSHARE, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: Sha'Tia Safford at 832-822-3100 in the Dept. of Orthopaedic Surgery & Scoliosis.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The IRB office number is (713) 798-6970. Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

If your child is the one invited to take part in this study you are signing to give your permission. Each child may agree to take part in a study at his or her own level of understanding. When you sign this you also note that your child understands and agrees to take part in this study according to his or her understanding.

Please print your child's name here

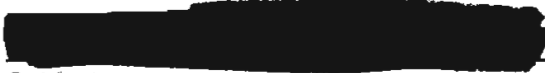



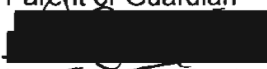




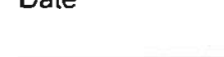
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Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

 Subject	 Date
 Legally Authorized Representative Parent or Guardian	 Date
 Investigator or Designee Obtaining Consent	 Date
 Witness (if applicable)	 Date
 Translator (if applicable)	 Date